REMARKS

This is a response to the Office Action mailed August 29, 2003. Claims 1-45 are pending in the application. Claims 1-13 have been rejected by the Examiner. As noted above, Applicant has amended Claim 1, and submitted New Claims 29-45. The amendments and New Claims are fully supported by the written description. Also, no new matter has been introduced into the application. The numbered paragraphs below correspond to the Examiner's numbered paragraphs:

Election/Restrictions

1. Applicant reaffirms election of Group I, Species 3 (Claims 1-13).

Claim Rejections – 35 USC § 112

2./3. The Examiner has rejected Claims 7 and 8 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. In particular, the Examiner has found that "[t]he limitation 'a third material carried by the stent to convert a third type of energy . . .' is not defined in the specification and the drawing."

According to Section 2164.01 of the Manual of Patent Examining Procedure (MPEP), the enablement requirement obliges that "the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation." MPEP, Section 2164.01 at 2100-178 (8th Edition, *rev.* Feb. 1, 2003) (citing *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988)). According to Section 2164.04 of the MPEP, "[i]n order to make a rejection, **the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention**." MPEP, Section 2164.04 at 2100-183 (citing *In re Wright*, 999 F.2d 1557, 1562 (Fed. Cir. 1993)) (emphasis added). Furthermore,

> [a] specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in

> describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.

Id. (citing *In re Marzocchi*, 439 F.2d 220, 224 (CCPA 1971)).

Applicant respectfully submits that the Examiner has failed to meet the initial burden of establishing a reasonable basis to question the enablement provided for the claimed invention. As noted above, the Examiner concluded that "[t]he limitation 'a third material carried by the stent to convert a third type of energy . . .' is not defined in the specification and the drawing." The enablement requirement does not oblige an applicant to "define" each and every limitation. Rather, the "test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." *United States v. Telectronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1988).

By referring to the disclosure of the current specification coupled with information known in the art, one reasonably skilled in the art could certainly make or use the invention as claimed by Claims 7 and 8 without undue experimentation. Claim 7 claims,

> [t]he stent of Claim 1, further comprising a third material carried by the stent configured to convert a third type of energy received by the third material from an energy source positioned external to the body vessel to a fourth type of energy, wherein the fourth type of energy promotes release of the therapeutic substance from the first material.

Moreover, Claim 8 claims "[t]he stent of Claim 7, wherein the first and third types of energy are electromagnetic energy, and wherein the electromagnetic energy of the first energy type has a different wavelength than the third energy type." The disclosure unquestionably teaches one having reasonable skill in the art how to make and use a stent that has more than one energy conversion material.

The specification clearly suggests that the energy conversion material can convert various

types of energy. For example, on pages 6 and 7, it is noted that "[e]nergy conversion material 32 can be any material that is capable of receiving a stimuli and converting such a stimuli to a form of energy. In one embodiment, for example, energy conversion material 32 is able to convert a first type of energy (e.g., electromagnetic, thermal, chemical) into a second type of energy (e.g., electromagnetic, thermal, chemical)." Furthermore, the specification teaches that there are different types of materials that can be used as energy conversion material. For instance, the specification on page 8 notes that "[o]ne of ordinary skill in the art will understand that energy conversion materials 32 besides Au particles are within the scope of the invention. For instance, ferrimagnetic glass-ceramics can be used as energy conversion material 32. These ferrimagnetic glass-ceramics can convert magnetic field energy to thermal energy." Also, the specification makes it clear that different energy conversion materials can be used on the same stent. For example, on pages 13 and 14 of the specification, it is noted that

> Alternatively, two or more different types of energy conversion materials can be used. For example, depots 30 at ends 14, 16 of stent 10 can carry Au particles, whereas depots 30 at mid-section 18 carry an Au-Cu alloy. By providing stent 10 with different types of energy conversion material 32, there can be a non-uniform response to energy emitted so that the delivery of the therapeutic substance can differ either spatially, or temporally. For example, in the case of Au particles, particles with different core-shell ratios will have different peak absorbance profiles. Referring to Figure 9, the absorbance spectra for particles A and B show that particle A has a different peak absorbance than particle B. By matching particle A with a carrier material that carries a different therapeutic substance than that matched with particle B, different therapeutic substances can be delivered at different wavelengths.

It is submitted that the Examiner has failed to meet the initial burden of establishing a reasonable basis to question the enablement. Applicant respectfully requests the Examiner to reconsider the Section 112 rejection.

4./5. The Examiner has rejected Claims 1-9 and 11-13 under 35 U.S.C. §102(b) as being anticipated by Fearnot et al. (U.S. Patent Number 5,609,629). Fearnot et al. is directed to a

method of applying a porous layer of a polymer by vapor or plasma deposition that can provide a controlled release of a bioactive material. (See Abstract). Fearnot et al. disclose that

> Applicants have discovered that the degradation of an agent, a drug or a bioactive material applied to such a device can be avoided by covering the agent, drug or bioactive material with a porous layer of a biocompatible polymer that is applied without the use of solvents, catalysts, heat or other chemicals or techniques, which would otherwise be likely to degrade or damage the agent, drug or material. **Those biocompatible polymers which can be applied by vapor deposition or plasma deposition, and which polymerize and cure merely upon condensation from the vapor phase, are expected to be useful for this purpose.**

(Col. 3, lines 6-17) (emphasis added).

According to the Federal Circuit, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). Fearnot et al. clearly fail to disclose all of the elements of amended Claim 1, such as a stent for delivering a therapeutic substance in a body vessel including:

> a first material carried by the stent containing a therapeutic substance; and
> **a second material carried by the stent configured to convert a first type of energy received by the second material from an energy source positioned external to the body vessel to a second type of energy, wherein the second type of energy promotes release of the therapeutic substance from the first material.**

In particular, Fearnot et al. do not disclose a second material that is "configured to convert a first type of energy received by the second material from an energy source positioned external to the body vessel to a second type of energy." The Examiner seems to suggest by the citations in the Office Action that the plasma of Fearnot et al. for the deposition process could act as the second material. Applicant respectfully submits it appears that the Examiner is misinterpreting the Fearnot et al. reference. According to Fearnot et al., "[p]lasma is an ionized gas maintained under vacuum and excited by electrical energy, typically in the radiofrequency range." Although this statement suggests that the plasma is able to convert electrical energy to chemical energy,

there is nothing in Fearnot et al. that suggests that the plasma is in fact ever carried by the stent. Instead, the plasma is merely used to deposit polymers on the stent during the deposition process. Also, there is no evidence in Fearnot et al. that the second type of energy "produced" by the plasma (i.e., the ionization or chemical energy) could promote the release of a therapeutic substance from another material present on the stent.

Furthermore, although Fearnot et al. disclose that gold can be used to construct the body of the stent (see col. 4, lines 48-51, and col. 7, lines 5-6), there is nothing in Fearnot et al. that suggest that the gold stent body would be configured to convert a first type of energy received by the gold body to a second type of energy. Also, there is nothing that suggests that the gold body would be able to produce a type of energy that would promote the release of a therapeutic substance from another type of material disposed on the stent. Accordingly, Claim 1 is allowable over Fearnot et al.

Fearnot et al. also fails to disclose all of the elements of the dependent claims of the present invention. For example, in contrast to Claim 4, there is nothing in Fearnot et al. that suggests that an energy conversion material is disposed in microdepots positioned on the surface of the stent. Fearnot et al. also do not disclose an energy conversion material configured to convert "non-cytotoxic electromagnetic waves" as claimed by Claim 9[1]. Fearnot et al. also fail to disclose that the first material is a "**temperature-sensitive hydrogel**" such as "N-isopropylacrylamide, polyoxyethylene-polyoxypropylene block copolymers, poly(acrylic acid) grafted pluronic copolymers, chitosan grafted pluronic copolymer, elastin mimetic polypeptides, and combinations and mixtures thereof" as claimed by Claims 11 and 13, respectively. Nor does Fearnot et al. disclose a "temperature-sensitive hydrogel" that is in thermal communication with

an energy conversion material as claimed by Claim 12.

5. Claims 9 and 10 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Fearnot et al. in view of Anderson et al. (U.S. Patent Number 6,254,634). Anderson et al. is directed to "a support material (e.g., a material useful for fabrication of medical articles), bearing an intermediate layer having **photoimmobilized thereon molecules of a target compound**. In another aspect, the present invention provides a method of **attaching** target molecules to support surfaces." (Col. 4, lines 12-17) (emphasis added). Anderson et al. disclose that "[r]eagents of the invention carry one or more pendent latent reactive (preferably photoreactive) groups **covalently bonded to the residue of the molecule**. . . . Latent reactive groups can be chosen that are responsive to various portions of the electromagnetic spectrum, with those responsive to ultraviolet, infrared and visible portions of the spectrum (referred to herein as "photoreactive") being particularly preferred." (Col. 7, lines 24-35) (emphasis added). Anderson et al. also disclose that "[u]pon activation of the photoreactive groups, **the reagent molecules are covalently bound to each other and/or to the intermediate layer by covalent bonds through residues of the photoreactive groups**." (Col. 8, lines 33-36) (emphasis added).

To establish *prima facie* obviousness, **all of the claimed limitations** must be taught or suggested in the references cited. *In re Royka*, 490 F.2d 981 (CCPA 1974). As noted above, Fearnot et al. fail to disclose all of the limitations of amended Claim 1. The disclosure of Anderson et al. fails to cure the deficiencies of the Fearnot et al. reference. Although Anderson et al. disclose a composition including reagents that are responsive to portions of the electromagnetic spectrum, the reagents in Anderson et al. serve a function that is directly in conflict with the energy conversion material of the present invention. The reagents in Anderson

[1] It is noted that the Examiner lists Claim 9 as one of the claims rejected under Section 102(b) on page 3 of the Office Action, but then admits on page 4 of the Office Action that "Fearnot et al do not disclose the first type of

et al. are in essence photoinitiators that are used to form covalent bonds between molecules. Electromagnetic energy causes the reagent to be placed in an excited state which creates a radical pair. (See Col. 7, lines 65-67 to Col. 8, line 1; "Benzophenone is a particularly preferred photoreactive moiety, since it is capable of photochemical excitation with the initial formation of an excited singlet state that undergoes intersystem crossing to the triplet state. The excited triplet state can insert into carbon-hydrogen bonds by abstraction of a hydrogen atom (from a support surface, for example), thus creating a radical pair.") Subsequent collapse of the radical pair leads to formation of a new carbon-carbon bond. (See Col. 8., lines 1-2). Having an energy conversion material that forms a covalent bond (e.g., a carbon-carbon bond) is directly contrary to the present invention. As claimed in the Claim 1, the energy conversion material of the present invention produces a type of energy that "promotes the release of the therapeutic substance from the first material." The photoinitiators of the Anderson et al. reference, on the other hand, prevent or hinder the release of a therapeutic agent. (See Col. 11, lines 31-32; "Photoheparin was then **photoimmobilized** onto the H-siloxane-treated stent in the following manner" (emphasis added); see also, Col. 14, lines 38-42; "The illumination duration is for 2 minutes at an intensity of 8-10 mW/cm^2 in the wavelength range of 330-340 nm to activate the latent benzophenone reaction to **photocouple** the PVP to the H-siloxane-benzophenone treated stent" (emphasis added)). Accordingly, Claims 9 and 10 are allowable over Fearnot et al. in view of Anderson et al.

Applicant also respectfully submits that the Examiner has failed to establish a *prima facie* case of obviousness because there would have been no suggestion or motivation to modify Fearnot et al. with the teachings of Anderson et al. in order to make the claimed invention. There are three possible sources for a motivation to combine references: "the nature of the

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energy is an electromagnetic waves."

problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art." *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998). **However, the mere fact that a prior art reference can be modified does not make the modification obvious unless the prior art also suggests the desirability of the modification**. *See In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984).

The functions of the reagents disclosed in Anderson et al. and the energy conversion materials of the present invention are totally different. In fact, combining the Anderson et al. reagents with the other components of the present invention could completely defeat the purpose of the present invention--namely, promoting the release of a therapeutic substance by remote activation. In short, the Anderson et al. reference **teaches away** from the combination of its disclosure with the Fearnot et al. reference. Therefore, there would have been no motivation to include the reagents of the Anderson et al. disclosure with the components of the Fearnot et al. reference to produce the claimed invention.

Additionally, Applicant also respectfully submits that the Examiner has failed to establish a *prima facie* case of obviousness because there would not have been a reasonable expectation of success of incorporating the elements of the Anderson et al. reference into the Fearnot et al. reference in order to produce the present invention. According to the Federal Circuit, the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. *See In re Merck & Co., Inc.*, 800 F2d 1091, 1097 (Fed Cir. 1986). **However, the reasonable expectation of success must be found in the prior art, and not based on applicant's disclosure**. *See In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991).

The prior art references do not provide the slightest hint or suggestion that there would be a reasonable expectation of success of manufacturing a stent that carries an energy conversion

material that can produce a type of energy that promotes the release of a therapeutic agent from the stent. As noted above, Anderson et al. merely disclose using photoinitiators to bond various chemical components to medical devices. This disclosure cannot support a finding of a reasonable expectation of success of producing the claimed invention.

It is submitted that the Examiner has improperly relied upon hindsight to combine the teachings of Fearnot et al. and Anderson et al. to arrive at the determination of obviousness. **As the Federal Circuit has found, it is impermissible to use the claimed invention as an instruction manual or "template" to piece together the teachings of the prior art so that the claimed invention is rendered obvious. The Examiner should not use hindsight reconstruction to pick and choose among the isolated disclosures in the prior art to "deprecate the claimed invention."** Accordingly, Applicant respectfully requests that the Examiner reconsider the finding of obviousness, and allow Claims 9 and 10.

CONCLUSION

Claims 1-45 are pending in this application. Applicant respectfully submits that the claims have been placed in condition for allowance. Applicants respectfully request the Examiner to enter the foregoing amendments and remarks and pass the case to issue.

If the Examiner has any questions or concerns, the Examiner is invited to telephone the undersigned attorney at (415) 954-0345.

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